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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/679,714

Applicant: A. Awad

Filed: October 6, 2003

Title: REDUCTION OF ACRYLAMIDE FORMATION IN COOKED STARCHY FOODS

Group Art Unit: 1794

Confirmation No.: 2884

Customer No.: 35684

Examiner: Viren A. Thakur

Attorney Docket No.: Awad-George 4.1-7 (000141461-0006)

REPLY BRIEF

MS Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This Reply Brief is filed in response to the Examiner's Answer (mailed March 17, 2010) for the pending appeal in this application, the Appeal Brief for which was filed on January 7, 2010.

The Examiner's Answer presented new grounds for rejection. Accordingly, the appellant hereby **maintains the appeal** with the filing of the present Reply Brief.

Any fee deficiencies may be charged, or any overpayment credited, to our deposit account 12-2136.

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I. Real Party in Interest

The real party in interest in this appeal is UrthTech, LLC of Farmington Hills, Michigan ("UrthTech"), the assignee of the entire right, title, and interest to the above-identified patent application, as evidenced by the assignment recorded in the United States Patent and Trademark Office ("PTO") at Reel 023700, Frame 0419 on December 24, 2009. This patent application was originally assigned by the inventor Aziz C. Awad to Michael E. George of Farmington Hills, Michigan ("George"), as evidenced by the assignment recorded in the PTO at Reel 014589, Frame 0964 on October 3, 2003.

II. Related Appeals and Interferences

There are no other appeals or interferences known to the appellant or the appellant's legal representative which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. Status of Claims

A. History

This application was filed with claims 1-18.

B. Current Status of Claims

Claims cancelled: 3, 5, and 15

Claims withdrawn from consideration but not cancelled: None

Claims pending: 1, 2, 4, 6-14, and 16-34

Claims allowed: None

Claims rejected: 1, 2, 4, 6-14, and 16-34

C. Claims on Appeal

The claims on appeal are claims 1, 2, 4, 6-14, 16-34.

IV. Status of Amendments

The most recent amendment to the claims was by a paper submitted on May 7, 2009 (Amendment "B"). Accordingly, the appellant understands the current form of the claims to be represented by Amendment "B" (reproduced in Section VIII below (Claims Appendix)).

V. Summary of Claimed Subject Matter

The disclosed subject matter generally relates to a process for the reduction of acrylamide formation in starchy foods when cooked at high temperature, particularly when they are baked or fried. The disclosed process addresses the problem of acrylamide formation in cooked starchy foods, generally baked or fried at temperatures above 120°C (e.g., potato chips, tortilla chips, pretzels, crackers, backed goods, fried breads, processed cereals, and French fries). The process of uses microbial cell fermentation to reduce acrylamide precursors (e.g., including mono- and di-saccharides and others) found in starchy foods prior to cooking. In particular, an uncooked starchy food product is treated with fermentative food grade bacteria and/or yeast under controlled pH and temperatures in the presence of growth stimulants (e.g., yeast extract, a neutralizing agent). Application specification, ¶ 2.

In the process, a raw, uncooked processed food (e.g., raw potato slices) is added to an aqueous medium in a fermenter (e.g., having an outlet strainer). *Id.*, ¶ 9 and ¶ 21. The raw, uncooked processed food initially contains sugars and asparagines; in some embodiments, however, the food is relatively low in sugar (e.g., <0.1 wt.% fructose, glucose, sucrose, maltose, and/or lactose) and no additional sugar is added to the food or aqueous medium. *Id.*, ¶ 9, ¶ 21, and ¶ 22. The aqueous medium has a pH between about 4 and 8 (e.g., about 4 and 5) and, in addition to the food, contains a microorganism used for food fermentations (e.g., yeast, bacterium), a yeast extract for fermentation by the microorganism, and a neutralizing agent (e.g., food grade acid, alkali metal hydroxide). *Id.*, ¶ 2, ¶ 9, and ¶ 12.

The aqueous medium is agitated (e.g., by recirculating fluid flow and/or with an impeller in the fermenter) while fermenting the food with the microorganisms so as to ferment the sugars initially in the food sufficiently to reduce the acrylamide production upon subsequent cooking of the food. *Id.*, ¶ 9, ¶ 21, ¶ 32, Figure 2, Figure 3. When the fermenter contains an outlet strainer, the aqueous medium and the food can be separated after fermentation by removing the aqueous medium through the outlet strainer. *Id.*, ¶ 26 and Figure 2. The fermented but uncooked food can be washed (e.g., with water) prior to cooking. *Id.*, Figure 1.

The fermented but uncooked food is then baked or fried to form a fermented and cooked food. *Id.*, ¶ 9 and ¶ 11. The fermented and cooked food contains less acrylamide than without the fermentation process (e.g., by simply baking or frying the raw, uncooked processed food). *Id.*, ¶ 9. Various factors such as microorganism type, microorganism amount, fermentation pH, fermentation temperature, fermentation time, and food type were investigated for their impact on the degree of acrylamide reduction relative to food cooked without first performing the recited fermentation process. *See id.,* ¶ 26-¶ 33 and Tables 2-10 (application examples). In many cases, particularly at lower pH values, the degree of acrylamide reduction is substantial, for example being about 50% or more

The foregoing discussion generally applies to independent claims 1, 20, 28, and 29, and the separately argued dependent claims. For the sake of clarity, however, the portions of the application specification correlating to the specific limitations of the claims are summarized in Tables 1a to 1e, below.

Table 1a. Specification References (Independent Claim 1)

1. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:	**Specification Reference**
(a) adding a raw, uncooked processed food comprising asparagine and sugars to a fermenter with an outlet strainer for straining fermented food, the fermenter containing an aqueous medium having a pH between about 4 and 8, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises: (i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food, (ii) yeast extract for fermentation by the microorganism, and (iii) a neutralizing agent comprising a food-grade acid or an alkali metal hydroxide;	¶ 2, ¶ 9, ¶ 12, ¶ 21, ¶ 22, Table 1
(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food;	¶ 9, ¶ 21, ¶ 32, Figure 1, Figure 2
(c) removing the aqueous medium from the uncooked processed food in the fermenter through the outlet strainer;	¶ 26, Figure 2
(d) washing the uncooked processed food from step (c); and	Figure 1
(e) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;	¶ 9, ¶ 11
wherein no sugars are added to the processed food through steps (a) to (e).	¶ 9

Table 1b. Specification References (Independent Claim 20)

20. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:	**Specification Reference**
(a) adding a raw, uncooked processed food comprising asparagine and sugars to a fermenter with an outlet strainer for straining fermented food, the fermenter containing an aqueous medium having a pH between about 4 and 5, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises: (i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food, (ii) yeast extract for fermentation by the microorganism, and (iii) a neutralizing agent comprising a food-grade acid or an alkali metal hydroxide;	¶ 2, ¶ 9, ¶ 12, ¶ 21, ¶ 22, Table 1
(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food;	¶ 9, ¶ 21, ¶ 32, Figure 1, Figure 2
(c) removing the aqueous medium from the uncooked processed food in the fermenter through the outlet strainer;	¶ 26, Figure 2
(d) washing the uncooked processed food from step (c); and	Figure 1
(e) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;	¶ 9, ¶ 11
wherein no sugars are added to the processed food through steps (a) to (e).	¶ 9

Table 1c. Specification References (Independent Claim 28)

28. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:	**Specification Reference**
(a) adding a raw, uncooked processed food comprising asparagine, sugars, and less than 0.1 wt.% fructose to a fermenter containing an aqueous medium having a pH between about 4 and 8, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises: (i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food, (ii) yeast extract for fermentation by the microorganism, and (iii) a neutralizing agent;	¶ 2, ¶ 9, ¶ 12, ¶ 21, ¶ 22, Table 1
(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food; and	¶ 9, ¶ 21, ¶ 32, Figure 1, Figure 2
(c) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;	¶ 9, ¶ 11
wherein no sugars are added to the processed food through steps (a) to (c).	¶ 9

Table 1d. Specification References (Independent Claim 29)

29. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:	**Specification Reference**
(a) adding a raw, uncooked processed food comprising asparagine, sugars, and less than 0.1 wt.% glucose to a fermenter containing an aqueous medium having a pH between about 4 and 8, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises: (i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food, (ii) yeast extract for fermentation by the microorganism, and (iii) a neutralizing agent;	¶ 2, ¶ 9, ¶ 12, ¶ 21, ¶ 22, Table 1
(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food; and	¶ 9, ¶ 21, ¶ 32, Figure 1, Figure 2
(c) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;	¶ 9, ¶ 11
wherein no sugars are added to the processed food through steps (a) to (c).	¶ 9

Table 1e. Specification References (Dependent Claims)

Dependent Claim	Specification Reference
4. The process of Claim 1 or 2 wherein the aqueous medium for the fermentation is at a temperature between about 10 and 40°C and the aqueous medium has a pH between about 4 and 5 at the end of the fermentation.	¶ 10, ¶ 12, ¶ 30-¶ 31, Tables 8-9
6. The process of Claim 1 or 2 wherein: (i) the uncooked processed food comprises potatoes, and (ii) step (e) comprises frying the uncooked processed food without drying the uncooked processed food after step (b) and before step (e).	Figure 1
16. The process of Claim 1 wherein at the end of the fermenting the aqueous medium has a pH between about 4 and 5.	¶ 12, ¶ 30-¶ 31, Tables 8-9
25. The process of Claim 20 wherein at the end of the fermenting the aqueous medium has a pH between about 4 and 5.	¶ 12, ¶ 30-¶ 31, Tables 8-9
26. The process of Claim 1 wherein the uncooked processed food added in step (a) comprises less than 0.1 wt.% glucose.	¶ 22, Table 1
27. The process of Claim 1 wherein the uncooked processed food added in step (a) comprises less than 0.1 wt.% fructose.	¶ 22, Table 1
30. The process of Claim 29 wherein the uncooked processed food added in step (a) comprises less than 0.1 wt.% fructose.	¶ 22, Table 1
31. The process of Claim 29 wherein the uncooked processed food added in step (a) comprises each of fructose, glucose, sucrose, maltose, and lactose at levels less than 0.1 wt.%.	¶ 22, Table 1
32. The process of Claim 29 wherein the fermented and cooked food that contains less acrylamide than without the fermentation has an acrylamide reduction of about 50% or more.	Application Examples (generally ¶ 26-¶ 33 and Tables 2-10)
33. The process of Claim 29 wherein the fermented and cooked food that contains less acrylamide than without the fermentation has an acrylamide reduction of about 50% to about 80%.	Application Examples (generally ¶ 26-¶ 33 and Tables 2-10)
34. The process of Claim 29 wherein the fermented and cooked food that contains less acrylamide than without the fermentation has an acrylamide reduction of about 70% to about 80%.	Application Examples (generally ¶ 26-¶ 33 and Tables 2-10)

VI. Grounds of Rejection to be Reviewed on Appeal

As a result of the most recent final office action mailed August 13, 2009, all pending claims stand rejected as obvious under 35 USC § 103:

The Examiner's Answer dated March 17, 2010 provided new grounds of rejection based on new combinations of the applied references already of record. Essentially, the Mottram, Baldwn, and Elder applied references, which were previously incorporated into the rejection of certain dependent claims only, are now incorporated into the rejection of all independent and dependent claims.

More particularly, as a result of the Examiner's Answer, all pending claims stand rejected as obvious under 35 USC § 103 as set forth below:

(1) claims 1, 2, 8-10, 13, 14, and 17-19 stand rejected as obvious over the following combination (**"Combination 1"**) of references:
   - (i) Hilton et al. U.S. Patent No. 4,140,801 ("Hilton") in view of
   - (ii) Christ et al. U.S. Patent No. 4,242,361 ("Christ"),
   - (iii) Howe et al. "Yeast Media, Solutions, and Stocks" (1991) ("Howe"),
   - (iv) *Catalog of Bacteria and Bacteriophages* (1992) ("Catalog"),
   - (v) Champagnat U.S. Patent No. 3,193,390 ("Champagnat"),
   - (vi) Lund "Detection of Microorganisms in Food" (2000) ("Lund"),
   - (vii) Green et al. U.S. Patent No. 3,891,771 ("Green"),
   - (viii) Annuk et al. U.S. Patent No. 5,316,776 ("Annuk"),
   - (ix) Sokolsky et al. U.S. Patent No. 1,676,166 ("Sokolsky"),
   - (x) Hopkins U.S. Patent No. 4,341,802 ("Hopkins"),
   - (xi) Young et al. U.S. Patent No. 3,886,046 ("Young"),
   - (xii) Pinnegar U.S. Patent No. 3,425,839 ("Pinnegar"), and
   - (xiii) Baldwin U.S. Patent No. 2,744,017 ("Baldwin"),
   - (xiv) Mottram et al. "Acrylamide is Formed in the Maillard Reaction," *Nature*, vol. 419, p. 448-449 (October 3, 2002) ("Mottram"), and
   - (xv) Elder et al. U.S. Publication No. 2004/0058054 ("Elder");

(2) claim 6 stands rejected over the following combination (**"Combination 2"**) of references:
   - (i) the references of **Combination 1**, further in view of
   - (ii) Greup et al. U.S. Patent No. 4,348,417 ("Greup");

(3) claim 7 stands rejected over the following combination ("**Combination 3**") of references:

- (i) the references of **Combination 1**, further in view of
- (ii) Gimmler et al. U.S. Patent No. 6,001,409 ("Gimmler"),
- (iii) Sunderland U.S. Patent No. 5,558,898 ("Sunderland"),

(4) claim 13 stands rejected over the following combination ("**Combination 4**") of references:

- (i) the references of **Combination 1**, further in view of
- (ii) Goering et al. U.S. Patent No. 4,428,967 ("Goering");

(5) claims 4, 11, 12, 16, and 20-25 stand rejected over the following combination ("**Combination 5**") of references:

- (i) the references of **Combination 1**, further in view of
- (ii) Hagiwara U.S. Patent No. 4,298,620 ("Hagiwara"),
- (iii) Bechtle U.S. Patent No. 3,818,109 ("Bechtle"),
- (iv) "Fermented Fruits and Vegetables, A Global Perspective" (1998),
- (v) Baldwin,
- (vi) The applicant's alleged admissions of prior art,
- (vii) "Lactic Acid Bacteria" (2001),
- (viii) "Yeast Fermentation" (1999), and
- (ix) "How to Restart a Stuck Fermentation" (2001);

(6) claims 26-34 stand rejected over the following combination ("**Combination 6**") of references:

- (i) the references of **Combination 1**, further in view of
- (ii) Amrein et al., "Potential of Acrylamide Formation, Sugars, and Free Asparagine in Potatoes: A Comparison of Cultivars and Farming Systems," *J. Agric. Food Chem.*, vol. 51, p. 5556-5560 (published on web July 30, 2003) ("Amrein"); and

Thus, the issue on appeal is whether pending claims 1, 2, 4, 6-14, and 16-34 are obvious. More specifically, the appellant presents the following specific issue for consideration on appeal:

> (1) Whether claims 1, 2, 4, 6-14, and 16-34 are obvious under 35 USC § 103(a) over Hilton, variously in view of the other 24 references listed above in references **Combinations 1-6**.

VII. Argument

Claims 1, 2, 4, 6-14, and 16-34 stand rejected as obvious over Hilton, variously in view of the other 24 references listed above in references **Combinations 1-6**. Examiner's Answer dated March 17, 2010, p. 2-16 ("Examiner's Answer").

For the purposes of issue (1) on appeal (*see* Section VI above), claims 1, 2, 4, 6-14, and 16-34 are grouped and argued as a single unit with claim 1 with respect to limitations that are common to each of the independent claims 1, 20, 28, and 29. For issue (1), several sub-combinations of claims are additionally argued separately with respect common limitations in the following additional groupings:

(a) Claims 1 and 20 (grouped with claim 1)
(b) Claims 4, 16, 20, and 25 (grouped with claim 20)
(c) Claim 6;
(d) Claims 26-34 (claims 27 and 28 grouped with claim 28, claims 26, 29, and 32-34 grouped with claim 29, claims 30 and 31 individually argued); and
(e) Claims 32-34 (each individually argued).

A. Obviousness Standard

The PTO bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *see also* MPEP § 2142 (8th ed., rev. 6, September 2007). A *prima facie* case of obviousness requires that each and every limitation of the claim is described or suggested by the prior art, or would have been obvious based on the knowledge of those of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Further, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Additionally, a *prima facie* case of obviousness based on a combination of prior art elements requires that the results of the combination would have been predictable. *See Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) ("[T]he Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a finite number of identified, predictable solutions." (citations omitted)) Thus, any analysis supporting an obviousness rejection should be made explicit and should

"identify a reason that would have prompted a person of ordinary skill in the art to combine the elements" in the manner claimed. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).

Even though a conclusion of obviousness "is in a sense necessarily a reconstruction based on hindsight reasoning," MPEP § 2145(X)(A) (citing *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971)), there are limits to its application. Specifically, hindsight reconstruction of a claimed invention *using the applicant's disclosure as a template* is impermissible and represents an insufficient basis to support a *prima facie* case of obviousness. The likelihood of impermissible hindsight increases along with the number and/or complexity of the claimed features asserted to be obvious. *See Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (explaining that "simply retrac[ing] the path of the inventor with hindsight, discount[ing] the number and complexity of alternatives ... is *always inappropriate* for an obviousness test" (emphasis added)). For instance, "one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d at 1075.

B. Disclosure of the Applied References

The disclosures of Hilton and the other 24 references relied upon in various capacities are addressed in detail below.

1. Hilton et al. U.S. Patent No. 4,140,801

Hilton is generally directed to a process for making potato products. Specifically, Hilton "relates to the preparation of highly dehydrated potato products exhibiting improved color characteristics upon frying, from potatoes which have undesirably high reducing sugar content." Hilton, 1:6-9. The dehydrated potato products are can be stored for at least several months without undue physical or chemical modification. *Id.*, 5:36-40. In general, the potatoes are first fermented to reduce their sugar content, and then the potatoes are dehydrated for storage until subsequent partial rehydration and frying. *Id.*, 1:9-17. The pre-dehydration reduction of sugar content reduces the yeasty taste of the final potato product, as compared to products that are fermented post-dehydration. *Id.* 1:17-22.

The starting potatoes have a high reducing sugar content, ranging from at least 1 wt.% up to 7 wt.%. *Id.* 2:37-43. The potatoes are subdivided to allow effective mixing with the fermentation yeast, for example by slicing and subsequently mashing the potatoes. *Id.* 2:44-53. After preliminary slicing, the potatoes are washed (e.g., with water) and blanched with hot water/steam to gelatinize a substantial portion of the potato starch. *Id.* 2:57-65, 7:17-20.

The mixture of potato solids forming a fermentation medium has a total moisture content up to 90 wt.%, including both free and combined moisture. *Id.* 3:9-17. Preferably, the moisture content ranges from about 75 wt.% to 85 wt.%, which simply represents the natural water content of the initial raw potatoes. *Id.* 3:18-24. The fermentation yeast is added to the fermentation medium as an aqueous slurry such that the yeast content of the fermentation medium ranges from about 0.1 wt.% to 1 wt.% on a solids basis. *Id.* 3:35-45. The potato solids are then fermented to reduce their sugar content (e.g., for at least 0.5 hr to reduce the sugar content preferably to a value of about 0.2 wt.% or less). *Id.* 3:51-60. The potato solids are then dried, for example forming potato flakes. *Id.* 4:15-17 and 4:25-27.

Hilton presents Examples I-V illustrating its disclosed process. *See generally id.*, 7:7-10:52. Potatoes having a range of initial reducing sugar contents were fermented, in particular ranging from about 1.4 wt.% to 6.3 wt.% (Example V), more commonly ranging from about 2 wt.% to 3 wt.% (Examples I-IV). The reducing sugars included glucose and fructose, and the initial glucose:fructose ratio ranged from about 1:1 (Example IV) to about 5:1 (Example III). Raw potatoes were sliced, dipped in a $NaHSO_3$ solution, blanched with steam, water-washed to remove excess starch, and then mashed in a meat grinder. *Id.*, 7:8-23. The mashed potatoes had a moisture content of about 80 wt.% and were combined with a 20 wt.% aqueous slurry of baker's yeast to provide 0.3 wt.% yeast on a solids basis, thereby forming a fermentation mixture also having a moisture content of about 80 wt.%.[1] *Id.*, 7:26-29.

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[1] On a 100 lb-basis, the raw potatoes contained 20 lb potato solids and 80 lb water contained/bound within the potato solids. Thus, 0.06 lb yeast was required to yield 0.3 wt.% yeast on solids basis (i.e., combined weight of potato solids and yeast). Accordingly, 0.3 lb of the 20%-yeast slurry was added to the mashed potatoes, thereby adding an additional 0.24 lb water to the potatoes. Therefore, the fermentation mixture contained 80.24 lb water (i.e., 80 wt.% water compared to the total mixture weight of 100.3 lb), the vast majority of which was contained/bound within the potato solids (i.e., 80 lb/80.24 lb, or about 99.7 wt.%).

2. Christ al. U.S. Patent No. 4,242,361

Christ is generally directed to a process for preparing sauerkraut. In the disclosed method, liquid is recycled from the bottom of a fermentation vessel to the top of the vessel to prevent dehydration of the fermenting sauerkraut. Christ, abstract and Figs. 1-3.

3. Howe et al., "Yeast Media, Solutions, and Stocks"

This web reference discloses a yeast-growth medium including: yeast extract, water, glucose, and peptone (pH 5.8). Howe, p. 2-3.

4. *Catalog of Bacteria and Bacteriophages*

The catalog generally discloses various media formulations. The two formulations cited by the office action include (1) yeast extract, water, skim milk, and tomato juice (pH 7.0), and (2) yeast extract, water, glucose, and other components (pH 6.3). Catalog, p. 415 (medium #17) and p. 452 (medium #1006).

5. Champagnat U.S. Patent No. 3,193,390

Champagnat is generally directed to the production of yeasts. The disclosed process produces food yeasts in a nutrient medium having a paraffinic feedstock. Champagnat, 1:26-29. A disclosed medium includes: yeast extract, water, n-hexadecane as the paraffinic nutrient, and other components. *Id*, 3:20-38.

6. Green al. U.S. Patent No. 3,891,771

Green is generally directed to a method for manufacturing fermented vegetable products, in particular the manufacture of pickles by the fermentation of cucumbers. Green, 1:3-6. The method is performed in a vessel having a foraminous screen at the base of the vessel and having a recirculation line at the bottom of the vessel to recirculate the liquid contents of the vessel. *Id*., 2:63-3:7 and Fig. 2.

7. Annuk et al. U.S. Patent No. 5,316,776

Annuk is generally directed to a fermentation method for milled grain products, and is cited by the action for the agitation of a fermentation medium. Annuk, 10:52-56 and Fig. 3.

8. Sokolsky et al. U.S. Patent No. 1,676,166

Sokolsky is generally directed to a process for providing a casein-based food product. Specifically, a spongy, coagulated casein curd is separated from its corresponding whey by draining, and the spongy curd is then washed with water to remove residual bacteria and other milk components. Sokolsky, 1:23-46.

9. Hopkins U.S. Patent No. 4,341,802

Hopkins is generally directed to the production of proteins with reduced nucleic acids and is cited by the action for its disclosure related to fermentation medium recycling. Hopkins, 1:5-8.

10. Young et al. U.S. Patent No. 3,886,046

Young is generally directed to a recycle fermentation process and is cited by the action for its disclosure related to fermentation medium recycling. Young, 1:25-32.

11. Pinnegar U.S. Patent No. 3,425,839

Pinnegar is generally directed to a continuous beer-making process and is cited by the action for its disclosure related to fermentation vessels including a filter. Pinnegar, 1:17-24.

12. Greup et al. U.S. Patent No. 4,348,417

Greup is generally directed to methods of preparing potato snacks and is cited by the action for it disclosure related to the frying of a fermented, potato-based food product. Greup, 1:59-60. In particular, a starch-containing component (e.g., potato flour), an active yeast, water, and a sugar fermentable by the yeast are mixed to form a dough mass that is fermented for a time and then fried in oil/fat. *Id.*, 2:6-15.

13. Gimmler et al. U.S. Patent No. 6,001,409

Gimmler is generally directed to masa corn-based food products and methods and is cited by the action for its disclosure related to its use of a corn-based food source. Gimmler, 3:50-62.

14. Sunderland U.S. Patent No. 5,558,898

Sunderland is generally directed to a continuous method of producing masa flour and is cited by the action for its disclosure related to its use of a corn-based food source. Sunderland, 2:7-21.

15. Mottram et al. "Acrylamide is Formed in the Maillard Reaction"

Mottram investigates the mechanism by which acrylamide can be generated from food components during heating (e.g., cooking). Asparagine and glucose were reacted at 185°C to form acrylamide, both in a phosphate buffer and (to a lesser extent) in a dry mixture. Mottram, p. 448, cols. 2-3. Asparagine and 2,3-butanedione (a dicarbonyl Maillard reaction product) also were reacted in a phosphate buffer and in a dry mixture at 185°C to form acrylamide. *Id*, p. 448, col. 3. Mottram concludes that "the almost exclusive formation of acrylamide from asparagine could explain the occurrence of acrylamide in cooked plant-based foods." *Id.*

16. Elder et al. U.S. Publication No. 2004/0058054

Elder is generally directed to a method for reducing acrylamide formation in thermally processed foods. The method relies on interfering with an acrylamide formation pathway that begins with asparagine. Elder, ¶ 2. Asparagine can be inactivated in the food by adding the enzyme asparaginase to decompose asparagine in the food to aspartic acid and ammonia. *Id.*, ¶ 11.

17. Goering et al. U.S. Patent No. 4,428,967

Goering is generally directed to processes for producing waxy barley products and is cited by the action for its disclosure related to yeast recycling. Goering, 1:13-19.

18. Baldwin U.S. Patent No. 2,744,017

Baldwin is generally directed to the enzymatic removal of sugars from food products, and is cited for its disclosure that lactic acid bacteria fermentation has been used address Maillard browing reactions. Baldwin, 1:27-45.

19. Hagiwara U.S. Patent No. 4,298,620

Hagiwara is generally directed to a tear grass fermentation product of a *Lactobacillus* strain. A water extract of tear grass is fermented with the *Lactobacillus* strain at an initial pH ranging from about 4-6 and a final pH ranging from about 3-4. Hagiwara, 4:53-60.

20. Bechtle U.S. Patent No. 3,818,109

Bechtle is generally directed to the conversion of whey solids to an edible yeast cell mass. Lactose-containing whey is converted with two or more bacterial species from *Lactobacillus*, *Streptococcus*, and *Leuconostoc*. Bechtle, 5:39-47. The initial fermentation pH ranges from 4.9 to 5.9, and is usually above 5.0. *Id.*, 7:36-44. Accumulation of lactic acid during fermentation results in an inhibitory, minimum pH ranging from 4.4 to 4.9, but eventual consumption of the lactic acid results in a final pH above 6.0 (e.g., 6.5-8.5). *Id.*, 8:56-9:15.

21. "Fermented Fruits and Vegetables"

This web reference is generally related to bacterial fermentations and is cited for its disclosure that lactic acid bacteria are used for sauerkraut fermentation. Fermented Fruits and Vegetables, section 5.6.2.

22. "Lactic Acid Bacteria"

This web reference is cited for its disclosure that the pH of a lactic acid fermentation can drop to values as low as 4.0 in fermented food products including yogurt, cheese, sauerkraut, and sausage. Lactic Acid Bacteria, p. 1. Lactic acid bacteria are sensitive to such low pH values, causing the fermentation and growth of the bacteria to be self-limiting. *Id.*

23. "Yeast Fermentation"

This web reference is generally related to a laboratory class exercise examining the growth characteristics of the yeast *Saccharomyces cerevisiae* and is cited for its disclosure that a pH value of 5 is optimum for *Saccharomyces cerevisiae* growth. Yeast Fermentation, section 1.

24. "How to Restart a Stuck Fermentation"

This web reference is generally related to a wine fermentation process and is cited for its disclosure that a pH value ranging from 3.4 to 5.5 is ideal for the wine fermentation of grape juice. How to Restart a Stuck Fermentation, p. 1.

25. Amrein et al., "Potential of Acrylamide Formation..."

Amrein relates to the analysis of different potato cultivars for glucose, fructose, sucrose, free asparagine, and free glutamine content. Amrein, abstract. Amrein is cited by the action as evidence that potato cultivars having less than 0.1 wt.% of various sugars exist.

C. Claims 1, 2, 4, 6-14, and 16-34

Hilton is the primary reference being modified in all of the pending obviousness rejections. Thus, for each of the many proposed modifications of Hilton, there must be a "reason that would have prompted a person of ordinary skill in the art to combine the elements" in the manner claimed. *KSR*, 550 U.S. at 418. Further, any proposed modification asserted in an obviousness rejection must not render the modified reference unsatisfactory (i.e., Hilton in this case) for its intended purpose. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

As is evident from the following sections, the obviousness rejections are based on impermissible hindsight. Other than the applicant's own disclosure, there is nothing that would have led the skilled artisan to the claimed methods from the isolated pieces of the prior art that disclose an element of the claimed methods but in a manner that is contextually removed from the primary reference being modified (i.e., Hilton). The fact that various elements of the claimed methods can be found in the prior art is insufficient. *See KSR*, 550 U.S. at 401 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."). "Thus, where the invention sought to be patented resides in a combination of old elements, the proper inquiry is whether bringing them together was obvious and not, whether one of ordinary skill, having the invention before him, would find it obvious through hindsight to reconstruct the invention from elements of the prior art." *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). In this case, however, the rationales offered in support of the various proposed modifications in the rejections

are unrelated to the problem solved by Hilton and do not take into account the inconsistencies and negative consequences that would follow from the proposed modification.

Essentially, the obviousness rejections stem from the identification of a reference (i.e., Hilton) that is tangentially related to the pending claims based on its use of a potato fermentation process. The Office Action then proceeds to assert that every difference between Hilton and the recited processes is obvious because the claimed element has at least some utility in at least some context. However, there is no regard for the final process that is asserted to result from the applied references, and there is no consideration how the proposed modifications fit together as a cohesive process that the skilled artisan would have in fact found obvious to perform.

Figure 1 below illustrates the Office Action's inappropriate use of "hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d at 1075. The left side of Figure 1 illustrates the general Hilton process that forms the basis for all of the assertedly obvious modifications. The right side of Figure 1 illustrates the final process that results from all of the incremental "obvious" changes to Hilton (highlighted boxes in the figure).

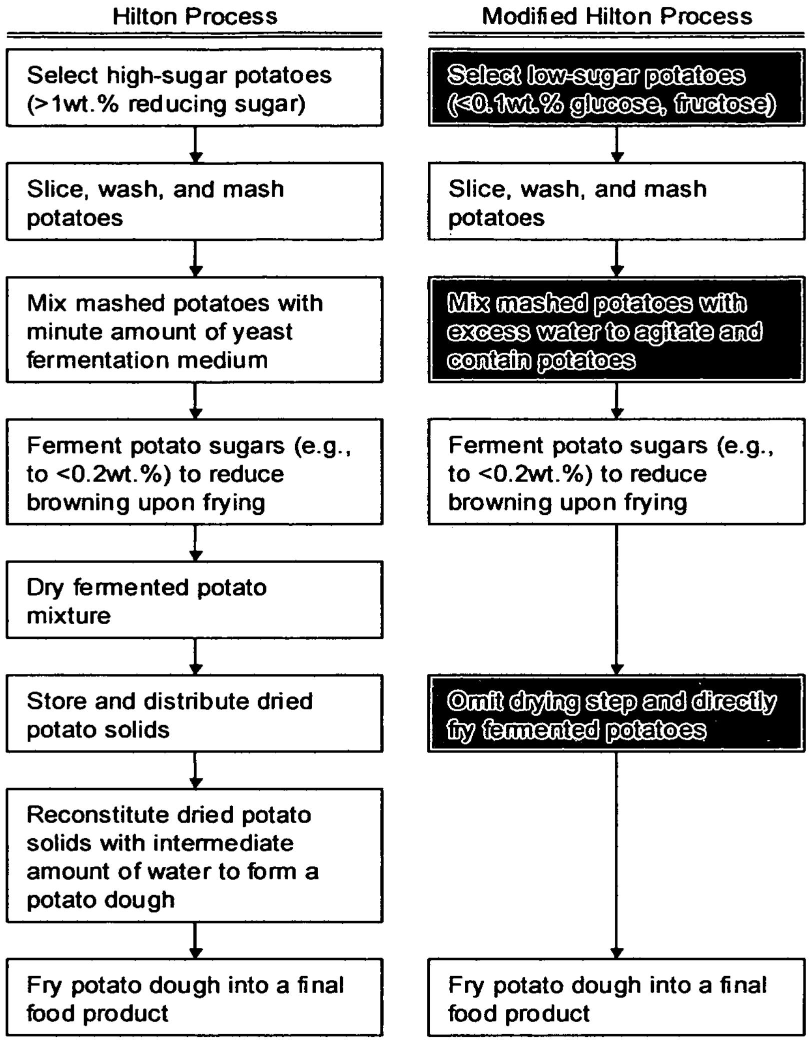

Figure 1. Base and Modified Hilton Processes

As is apparent from Figure 1 and as is discussed in detail in the following sections, the resulting process on the right side of Figure 1 is simply an arbitrary collection of process steps which, *when viewed as a whole*, are internally inconsistent and would not have been well-suited to achieve any particular goal. For example, the selection of low-sugar potatoes having less than 0.1 wt.% glucose and/or less than 0.1 wt.% fructose as a starting material in the modified process is inconsistent with the subsequent fermentation step, which only requires reduction to less than 0.2 wt.% to avoid undesirable browning. Similarly, the addition of excess water to form an aqueous mixture in the modified process is inconsistent with the

subsequent omission of the drying step that would otherwise form dried potato solids capable of dough formation and frying. As evident from Figure 1 and the following sections, the net result of the approach followed by the Office Action is a simple retracing the path of the inventor using the applicant's disclosure without regard for the number and complexity of alternatives along the path – a hallmark of impermissible hindsight. *Ortho-McNeil*, 520 F.3d at 1364.

1. Aqueous Medium

Claims 1, 20, 28, and 29 recite adding a raw, uncooked processed food to a fermenter containing an aqueous medium such that the aqueous medium then contains the uncooked processed food. Claims 1, 20, 28, and 29 further recite agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium.

The action asserts that the aqueous medium limitation is satisfied by Hilton's disclosure of the addition of a minute amount of an aqueous yeast slurry to a large excess of mashed potatoes. Examiner's Answer, p. 7-8 and 33 (referring to Hilton's Example 1).

Hilton discloses a mashed potato matrix as a fermentation medium that is not an aqueous medium. *See* Section VII.B.1 above; *see also* Awad Declaration, ¶ 13. Hilton's potato solids to be fermented have a total moisture content up to 90 wt.%; however, this high moisture content represents the natural water content of the initial raw potatoes. *See* Section VII.B.1 above. There is no substantial amount of free water (i.e., water not absorbed or otherwise bound within the potato solids) capable of forming an aqueous medium that contains the uncooked processed food or that can be agitated in the fermenter. The addition of yeast to the potato solids of Hilton does not change the character of the fermentation medium, even though the yeast is added in the form of an aqueous slurry. Specifically, the yeast is added to the potato solids in such a small amount that the additional water from the yeast slurry is insufficient to form an aqueous medium. *See id.* (analyzing the examples of Hilton and determining that 99.7 wt.% of the water content of the fermentation medium is bound within the mashed potato solids). Even though Hilton describes its fermentation medium as "aqueous in nature" (Hilton, 3:35-36), it is apparent from the context of Hilton that the "aqueous" label is based on the high natural water content

of potatoes in general. However, the high natural water content is bound within the potatoes and incapable of forming the recited aqueous medium.

In an attempt to remedy this deficiency, the action asserts that it would have been obvious to add an excess of water to Hilton's pre-fermentation mashed potato matrix mixture to ensure complete contact between the fermentation medium and the product to be fermented. Examiner's Answer, p. 34.

There is no reason, however, that the skilled artisan would have added the additional water to Hilton's pre-fermentation mixture. Hilton's pre-fermentation matrix is a mixture of mashed potatoes with sufficient water to already allow complete mixing and contact with the minute amount of yeast slurry. Moreover, the addition of excess water is completely counterproductive to Hilton's drying step to form dried flakes suitable for subsequent dough formation and frying. In particular, the addition of excess water would not be expected to provide a benefit during the fermentation step, yet it would substantially increase the energy requirement for subsequent drying of the fermented potatoes.

In view of the foregoing, there is no reason that the skilled artisan would have modified Hilton to obtain an aqueous medium as recited. Thus, the appellant submits that there is no *prima facie* case of obviousness for all pending claims, *KSR*, 550 U.S. at 418, and accordingly requests reversal of the obviousness rejections.

2. Yeast Extract

Independent claims 1, 20, 28, and 29 recite an aqueous medium comprising (i) a microorganism used for food fermentations for metabolizing sugars in an uncooked processed food and (ii) yeast extract for fermentation by the microorganism. Further, no additional sugars are added to the processed food in the recited process steps.

The rejection asserts that it would have been obvious to add a yeast extract to the system of Hilton to provide a nutrient source for Hilton's microorganisms, based in part on the assertion that "it has been well known in the art to use yeast extract for providing a nutrient medium for the microorganism" and that "it has been well known to the ordinarily skilled artisan that yeast and other microorganisms require nutrients in order to ferment a food." Examiner's Answer, p. 9-10.

Hilton, however, uses potatoes having an initially high reducing sugar content of at least 1 wt.%, more commonly ranging from about 2 wt.% to 3 wt.%. *See* Section VII.B.1 above. Thus, there would have been no reason to add a second nutrient source (i.e., the yeast extract) in addition to the pre-existing nutrient source (i.e., natural sugar content of the potatoes). Awad Declaration, ¶ 6. Specifically, within the context of Hilton and the other applied references, the fermentation need only take place as long as available sugars are present. *Id.*; *see also* Hilton, 3:51-60 (indicating the fermentation is performed until the reducing sugar content has been sufficiently reduced). Further, the addition of yeast extract to Hilton could have been counterproductive, possibly limiting the rate of sugar reduction by Hilton's yeast due to the presence of a competing nutrient source (i.e., the yeast extract in addition to the natural reducing sugar content). Awad Declaration, ¶ 6. Thus, there is no reason to modify the applied combination of references to arrive at the recited addition of yeast extract. *KSR*, 550 U.S. at 418. Further, the appellant submits that the Office Action's reliance on isolated disclosures of yeast extract and discounting of the chemical constituents of Hilton's base fermentation system represents impermissible hindsight reconstruction of the claimed processes. *In re Fine*, 837 F.2d at 1075.

Additionally, the applied references generally disclose the use of a yeast extract *in combination with other nutrients*, in particular sugars. Awad Declaration, ¶ 7; *see also* Sections VII.B.3-VII.B.5 above (secondary references disclosing yeast extract). The addition of supplemental sugar sources (e.g., outside of the natural sugar content of the raw food and the yeast extract) is contrary to the recitation that no sugars are added to the processed food. The obviousness rejections provide no reason why the skilled artisan would have selectively ignored portions of the secondary references to incorporate a yeast extract without a supplemental nutrient source. Accordingly, the applied references, even if combined as proposed in the action, fail to teach or suggest all recited limitations, and there can be no *prima face* case of obviousness. *In re Fine*, 837 F.2d at 1074.

The Examiner's Answer discounts the foregoing arguments, asserting that "it is only Appellant's opinion that the use of yeast extract would be counterproductive" and further that "additional sugars and nutrients present through the yeast extract could also have facilitated or even increased the rate of growth of the microorganisms, thus improving the rate of fermentation." Examiner's Answer, p. 35-

36. However, the argument regarding yeast extract as a counterproductive, competing food source in Hilton is not simply opinion; rather, it is a reasoned, scientific statement set forth in the Rule 132 declaration of Aziz C. Awad, the inventor of the present application who holds a Ph.D. in Food Science/Food Chemistry. Awad Declaration, ¶ 1. The Awad Declaration sets forth specific scientific reasoning based on common principles of mass transfer and diffusion why a yeast extract added to Hilton would likely provide a preferential, competing nutrient source that would inhibit Hilton's desired goal of fermenting reducing sugars:

> In particular, the yeast extract likely would be preferentially consumed before the reducing sugars (i.e., if added to Hilton's system), because the yeast extract would be more readily available in the fermentation medium than the reducing sugars. The yeast extract is dissolved or suspended in the aqueous medium; however, the reducing sugars must leach out of the potatoes to the aqueous medium before they are acted on by the microorganisms.

Awad Declaration, ¶ 6. In contrast to the foregoing, the Examiner's Answer does not provide any reason to doubt the declaration statement, and instead simply makes the naked assertion that the addition of yeast extract to Hiton's system "could have" improved the rate of fermentation.

The Examiner's Answer further asserts that the inclusion of "yeast extract would have been an obvious result effective variable, routinely determined by experimentation, for the purpose of achieving the requisite degree of yeast growth commensurate with the desired rate of fermentation." Examiner's Answer, p. 36. However, the concept of routine optimization applies to the determination of a workable range for a composition component when the prior art already establishes the desirability of incorporating the component in the first instance. *See In re Aller*, 220 F.2d 454, 456, (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."); MPEP § 2144.05(II)(A). In this case, the particular level of yeast extract is not recited in the claim, and there is nothing to be optimized in relation to the recited claim limitations and the applied references. Accordingly, the mere fact that yeast extract *per se* is known in the art does not establish any reason why the skilled artisan would have incorporated the yeast

extract into the Hilton process, and there is no *prima facie* case of obviousness. *KSR*, 550 U.S. at 418.

Accordingly, the appellant submits that the foregoing represents a sufficient basis to reverse the obviousness rejection of all pending claims, all of which recite the yeast extract and no addition of sugars to the processed food.

D. Claims 1 and 20

Independent claims 1 and 20 recite a fermenter with an outlet strainer and further recite washing the uncooked processed food from step (c) in the fermenter by introducing water to remove residues on the uncooked processed food from the fermentation through the outlet strainer.

The rejection relies on the teaching of Sokolsky to conclude that it would have been obvious to wash the fermented food product of Hilton. Examiner's Answer, p. 14-15.

However, it is not possible to wash the fermented food product of Hilton, because Hilton uses *blanched mashed potatoes*. Specifically, the fermented potato matrix of Hilton will not permit washing because of its mashed, dough-like consistency. *See* Section VII.B.1 and Awad Declaration, ¶ 13 In contrast, the spongy curd matrix of Sokolsky is amenable to washing because of its porous nature, which allows a washing fluid to flow through the matrix with a high surface contact area. Thus, even assuming that the skilled artisan would be motivated to incorporate the washing step of Sokolsky into the method of Hilton, there is no expectation that such a washing step would be effective or even possible.

The rejection relies on the teachings of Green and Christ to conclude that it would have been obvious to add an outlet strainer to the apparatus and process of Hilton. Examiner's Answer, p. 12-13.

However, an outlet strainer would have been ineffective or counter-productive in the apparatus of Hilton for the reasons above related to washing. Namely, the mashed potato matrix of Hilton would likely either plug the outlet strainer or be forced through the strainer along with the washing fluid (i.e., depending on the size of the strainer orifices and the flow rate of the washing fluid). In contrast, Green and Christ

relate to pickle and sauerkraut processes (respectively) that are amendable to the use of a strainer because of the larger, cohesive solid structure of their fermented solids (i.e., as compared to the small, mashed potato solids). In any event, an outlet strainer added to the apparatus of Hilton would not have the desired effect of retaining the fermented food product while permitting the washing fluid to pass through the outlet strainer.

Thus, the skilled artisan would not have reasonably predicted that a washing step or an outlet strainer could be successfully implemented into the Hilton process, and there can be no *prima facie* case of obviousness. *Eisai*, 533 F.3d at 1359.

E. Claims 4, 16, 20, and 25

Claims 4, 16, 20, and 25 recite a pH between about 4 and 5 for the aqueous medium, either in the initial or final fermentation medium. The appellant submits that objective evidence of non-obviousness in the form of comparative data present in the application specification provides an additional reason for reversal of the obviousness rejection of claims 4, 16, 20, and 25.

The application specification presents acrylamide reduction data for fermented and fried foods prepared according to the recited processes. Example 5 illustrates that the acrylamide reduction at pH values of 4 and 5 is substantially higher than at pH values from 6 to 8. Specification, ¶ 30 (Tables 8 and 9). The benefit of using a lower pH was demonstrated to be applicable to different types of microorganisms, including yeast and bacterial cells. *Id.* Similarly, substantial acrylamide reduction was observed in a variety of starch-based processed foods, including potato chips, processed cereal mix, and corn tortilla chip masa. *Id.*, ¶ 32 (Example 6, Table 10). Table 1 below compiles the acrylamide reduction data summarized in specification data Tables 2-10 as a function of pH (i.e., and taking into account other process variables such as microorganism type, fermentation time, fermentation temperature, and food type):

Table 1. Acrylamide Reduction as a Function of pH

	Percent Reduction in Acrylamide Formation							
pH	<20	20-29	30-39	40-49	50-59	60-69	70-79	80-89
4						1	2	2
5						1	1	
6	4	12		1	4	6	1	
7		1		1				
8		1	1					

The superior acrylamide reduction at lower pH values was unexpected, inasmuch as the *optimal pH for microbial growth of the microorganisms tested* was higher: pH of 6 to 7. Specification, ¶ 31; Awad Declaration, ¶ 8 and ¶ 11. The higher pH values are optimum for the fermentation growth of microorganisms; even if some microorganisms are capable of surviving at a lower pH, the lower pH is generally inhibitory for bacterial growth and would not have been expected to result in superior acrylamide reduction. Awad Declaration, ¶ 8. This indicates that a low pH has an independent effect on the reduction of acrylamide regardless of the presence and/or disappearance of acrylamide precursors (e.g., mono- and di-saccharides, which are reactants of the Maillard reaction), further illustrating that acrylamide formation cannot be fully explained by the Maillard reaction and that some other mechanism probably operates to reduce acrylamide. *Id.*, ¶ 11. Thus, the acrylamide reduction at pH values between about 4 and 5 is both substantial and unexpected, given that the low-pH optimum could not have been predicted on the based on the skilled artisan's knowledge.

The rejection relies on several references that are asserted to suggest the modification of Hilton to the lower pH values recited in the claims. However, the relied-upon references merely disclose that a lower pH value can be suitable for some fermentations, and they are completely unrelated to the specific potato-based fermentation of Hilton: (i) tear grass fermentation (Hagiwara), (ii) lactic acid bacteria fermentation in yogurt, cheese, sauerkraut, and sausage (Lactic Acid Bacteria), (iii) wine fermentation of grape juice (How to Restart a Stuck Fermentation), and (iv) classroom aqueous fermentation of glucose and glycerol (Yeast Fermentation). Thus, the relied-upon references are completely out of context with respect to the

Hilton reference being modified, so there is no reason that the skilled artisan would have incorporated such teachings into the Hilton process to arrive at the claimed method. *KSR*, 550 U.S. at 418.

Further, the identification of the recited range of pH values between about 4 and 5 would not have been a matter of routine optimization. Only result-effective variables can be optimized. MPEP § 2144.05(II)(B). Specifically, a particular parameter must first be recognized as a result-effective variable (i.e., a variable which achieves a recognized result) before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618 (CCPA 1977). Even assuming the desirability of limiting acrylamide, however, there is nothing in the applied references suggesting that the pH is a result-effective variable for acrylamide reduction. Thus, if the skilled artisan were to optimize the pH value of Hilton's system, it would have been for some purpose other than acrylamide reduction, and the optimization process would not necessarily lead the skilled artisan to the claimed range. As indicated above, for example, the optimal pH for microbial growth of the microorganisms tested was in the pH range of 6 to 7 (Specification, ¶ 31; Awad Declaration, ¶ 8 and ¶ 11), so such an optimization process would lead the skilled artisan away from the claimed range. Accordingly, the skilled artisan would not have been able to identify the lower recited pH range as a simple matter of routine optimization.

Accordingly, the appellant submits that the foregoing represents a sufficient demonstration of unexpected results for the processes of claims 4, 16, 20, and 25.

F. Claim 6

Dependent claim 6 recites that (i) the uncooked processed food comprises potatoes, and (ii) step (e) comprises frying the uncooked processed food without drying the uncooked processed food after step (b) and before step (e).

In Hilton, fermented potato solids are dried prior to storage and/or subsequent frying. Hilton, 4:15-17 and 5:36-46. The rejection asserts that it would have been obvious to omit Hilton's drying/dehydration step either as a matter of routine optimization or based on Greup's disclosure of a fermented, potato flour-based dough that is subsequently fried. Examiner's Answer, p. 21-22.

The appellant asserts, however, that there is no reason to omit the drying step of Hilton, whether based on routine optimization, Greup, or otherwise. Hilton's drying step is *not* simply a means to achieve any desired moisture level; rather, the drying step is performed to achieve "highly or extensively dehydrated" potato solids. Hilton, 4:17-19. The purpose of Hilton is to provide a dehydrated potato solids product that can be stably stored for several months without degradation and that can be distributed over a wide geographical area (i.e., based on its stable, low-weight dehydrated form). Hilton, 5:36-43. Thus, the rejection's proposed omission of the drying step would render the primary Hilton process unsatisfactory for its intended purpose of providing stable, dehydrated potato solids that have favorable browning characteristics. *In re Gordon*, 733 F.2d at 902.

The rejection further asserts that "the secondary function of drying is to achieve a desired moisture content for achieving the desired organoleptic properties when frying." Office Action dated August 13, 2009 at p. 5. This assertion regarding organoleptic properties is not supported by Hilton, the other applied references, or reasoning presented in the Office Action. In any event, the only disclosed purpose of an "intermediate moisture content" (i.e., a moisture level between the highly hydrated form used for fermentation and the highly dehydrated form used to storage/shipping) is to form a dough that can be shaped/formed into a desired food shape (e.g., chips). Hilton, 5:46-56. Thus, even if the skilled artisan were to omit the extensive dehydration process of Hilton, the skilled artisan would still need to dry the highly hydrated potato solids used for fermentation to arrive at an intermediate moisture content suitable for dough formation and shaping. In this case, the resulting process would still include a drying step and the recited claim limitation would not be met, precluding a *prima facie* conclusion of obviousness. *In re Fine*, 837 F.2d at 1074.

In view of the foregoing, the appellant requests reversal of the obviousness rejection of claim 6 for this additional reason.

G. Claims 26-34

Claims 26-31 recite that the raw, uncooked processed food added to the fermenter in the process step (a) alternatively comprise less than 0.1 wt.% fructose (claims 27 and 28), less than 0.1 wt.% glucose (claims 26 and 29), or a combination thereof (claims 30 and 31).

Hilton is explicitly directed to the fermentation of high reducing sugar-content potatoes. The starting potatoes have a reducing sugar content of at least 1 wt.%, where the reducing sugar has a glucose:fructose ratio ranging from about 1:1 to about 5:1, and the final reducing sugar content is preferably less than about 0.2 wt.%. *See* Section VII.B.1 above. Thus, the starting potatoes have an initial glucose content of at least about 0.5 wt.% to about 0.83 wt.% and an initial fructose content of at least about 0.17 wt.% to about 0.5 wt.%.

The rejection asserts that the selection of conventional potatoes having a lower sugar content within the recited range would have been an obvious optimization process:

> Therefore, once the art recognized that the sugars in the potatoes can be reduced and thus the browning upon frying can be controlled as a result of fermentation using microorganisms such as yeast, the particular conventional potatoes that one chose to treat would have been an obvious matter of choice and/or design.

Examiner's Answer, p. 27.

However, there is no reason that the skilled artisan would modify the process of Hilton to *simultaneously* (1) begin its process with low-sugar potatoes *and* (2) still ferment the low-sugar potatoes. If the skilled artisan had selected low-sugar potatoes meeting the recited fructose/glucose content, the skilled artisan also would have omitted Hilton's fermentation step, inasmuch as the recited saccharide contents are already below Hilton's most preferred final reducing sugar content of about 0.2 wt.% or less. Put another way, selection of potatoes having less than 0.1 wt.% fructose and/or less than 0.1 wt.% glucose would have been viewed as a sufficient condition for reducing potato browning upon frying, so there would have been no need to select the low-sugar potatoes and then perform a fermentation step for no added benefit. Thus, in view of the applied references, the skilled artisan might have (1) selected high-sugar potatoes for fermentation and subsequent drying/frying *or* (2) selected low-sugar potatoes for direct drying and frying, but the skilled artisan would not have simultaneously selected both features for incorporation into a potato processing method.

In view of the foregoing, there is no "reason that would have prompted a person of ordinary skill in the art to combine the elements" in the manner claimed. *KSR*, 550 U.S. at 418. Accordingly, the appellant submits that there is no *prima facie*

case of obviousness for claims 26-34 and that the claims are allowable for this independent reason.

In response to the foregoing arguments, the Examiner's Answer distinguishes the claimed limitations and the Hilton disclosure on the basis that claims use the open transition "comprising" in relation to the recited upper values of glucose, fructose, and/or other sugars. Examiner's Answer, p. 32. Presumably, this is intended to suggest that the skilled artisan could select potato material for Hilton's process that simultaneously meets (a) Hilton's requirement of at least 1 wt.% reducing sugar in the starting potato material and (b) the recited limitation of less than 0.1 wt.% glucose or fructose in the initial raw, uncooked food.

This reasoning in the Examiner's Answer fails in several respects. The particular level of individual sugars (e.g., reducing sugars such as glucose and fructose or other non-reducing sugars) in a starting food material (e.g., potatoes as in Hilton) is not an independent variable that the skilled artisan can choose *a priori*. While the skilled artisan might choose a particular potato cultivar for the cultivar's overall sugar profile, the individual sugars are present in the potato in certain ranges based on the cultivar selection. For example, it is not generally possible for the skilled artisan to arbitrarily select a potato cultivar simultaneously having less than 0.1 wt.% glucose (and/or less than 0.1 wt.% fructose) and having at least 1 wt.% reducing sugar. The Examiner's Answer provides no rationale how such a selection could be made, and the references of record indicate that no such selection is possible. In Hilton's Examples III and IV[2], for instance, the initial reducing sugar content is greater than 1 wt.%, and both glucose and fructose have an initial content greater than 0.1 wt.%. *See* Hilton, col. 9 (Tables II and III providing the sugar profiles at an initial fermentation time t = 0). Similarly, all of Amrein's listed potato cultivars that have less than 0.1 wt.% (equivalent to 1,000 mg/kg) glucose, less than 0.1 wt.% fructose, or both also have less than 1 wt.% (equivalent to 10,000 mg/kg) reducing

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[2] Hilton's Examples III and IV are those that report both the reducing sugar content of the potatoes as well as the corresponding distribution of glucose and fructose, which together sum to the reducing sugar content.

sugar. Amrein, p. 5558 (Table 1 providing sugar and amino profiles of different potato cultivars[3]).

Thus, notwithstanding the open "comprising" transition, the appellant submits that the skilled artisan could not select (and would not have a reason in the first instance to select) an initial food product that is consistent with the teaching of Hilton and has at least 1 wt.% reducing sugar and also has either less than 1 wt.% glucose (claims 26 and 29) or less than 1 wt.% fructose (claims 27 and 28). Further, claims 30 (reciting less than 1 wt.% fructose and glucose) and 31 (reciting less than 1 wt.% fructose, glucose, sucrose, maltose, and lactose) are more restrictive and there is no suggestion that such selections could be made consistent with the teaching of Hilton.

H. Claims 32-34

Claims 32-34 recite specific acrylamide reduction values for the fermented and cooked food that contains less acrylamide than without the fermentation: (i) about 50% or more (claim 32), (ii) about 50% to about 80% (claim 33), and (iii) about 70% to about 80% (claim 34). The appellant submits that objective evidence of non-obviousness in the form of comparative data present in the application specification provides an additional reason for reversal of the obviousness rejection of claims 32-34.

The application specification presents acrylamide reduction data for fermented and fried foods prepared according to the recited processes. The data are summarized in Table 1 from Section VII.E above. Similar to the reasons presented in Section VII.E above (i.e., related to the pH-effect on acrylamide reduction), the data indicate that the recited acrylamide reduction is both significant and unexpected. In particular, the skilled artisan could not have expected to have been able to achieve the particularly recited acrylamide reduction levels by simply fermenting a raw, uncooked processed food comprising asparagine and sugars under any desired fermentation conditions. Specifically, the data in Table 1 indicate that many selections of fermentation conditions led to an acrylamide reduction in the range of about 20-29% (i.e., well below the recited threshold value of about 50%).

[3] From Amrein's Table 1, the reducing sugar content is taken as the sum of glucose and fructose, insofar as sucrose is not a reducing sugar and asparagine and glutamine are amino acids.

Accordingly, the appellant submits that the foregoing represents a sufficient demonstration of unexpected results for the processes of claims 32, 33, and 34. Additionally, the appellant further submits that claims 33 and 34 are separately and independently allowable in relation to claim 32 because they recite successively narrower acrylamide reduction values relative to claim 32 that encompass the data in the application specification.

I. Conclusion

The appellant submits that claims 1, 2, 4, 6-14, and 16-34 are non-obvious in view of the foregoing. Accordingly, the appellant respectfully requests reversal of the obviousness rejections.

Respectfully,

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VIII. Claims Appendix

1. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:

(a) adding a raw, uncooked processed food comprising asparagine and sugars to a fermenter with an outlet strainer for straining fermented food, the fermenter containing an aqueous medium having a pH between about 4 and 8, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises:

(i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food,

(ii) yeast extract for fermentation by the microorganism, and

(iii) a neutralizing agent comprising a food-grade acid or an alkali metal hydroxide;

(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food;

(c) removing the aqueous medium from the uncooked processed food in the fermenter through the outlet strainer;

(d) washing the uncooked processed food from step (c); and

(e) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;

wherein no sugars are added to the processed food through steps (a) to (e).

2. The process of Claim 1 wherein the yeast extract is introduced in dry form into the aqueous medium.

4. The process of Claim 1 or 2 wherein the aqueous medium for the fermentation is at a temperature between about 10 and 40°C and the aqueous medium has a pH between about 4 and 5 at the end of the fermentation.

6. The process of Claim 1 or 2 wherein:

(i) the uncooked processed food comprises potatoes, and

(ii) step (e) comprises frying the uncooked processed food without drying the uncooked processed food after step (b) and before step (e).

7. The process of Claim 1 or 2 wherein:

(i) the uncooked processed food is selected from the group consisting of cereal meals and corn meals, and

(ii) the uncooked processed food is dried after step (b) and before the cooking in step (e), and

(iii) step (e) comprises baking the uncooked processed food in an oven.

8. The process of Claim 1 wherein the cooked food is selected from the group consisting of potato chips, tortilla chips, pretzels, crackers, baked goods, fried breads, processed cereals and French fries.

9. The process of Claim 1 wherein the aqueous medium is recirculated into and out of the fermenter while retaining the food in the fermenter.

10. The process of Claim 1 or 2 wherein the microorganism is a yeast.

11. The process of Claim 1 or 2 wherein the microorganism is a bacterium.

12. The process of Claim 1 or 2 wherein the microorganism is a lactic acid producing microorganism.

13. The process of Claim 1 wherein the microorganism is recycled between batches of the uncooked processed food which are processed in the fermenter.

14. The process of Claim 1 wherein the pH of the aqueous medium is adjusted prior to the fermentation.

16. The process of Claim 1 wherein at the end of the fermenting the aqueous medium has a pH between about 4 and 5.

17. The process of Claim 1 wherein the uncooked processed food is dried after the fermentation and before the cooking in step (e).

18. The process of Claim 1 wherein water provided in the aqueous medium in step (a) is distilled or otherwise purified.

19. The process of Claim 1 wherein the uncooked processed food is potato slices.

20. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:

(a) adding a raw, uncooked processed food comprising asparagine and sugars to a fermenter with an outlet strainer for straining fermented food, the fermenter containing an aqueous medium having a pH between about 4 and 5, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises:

(i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food,

(ii) yeast extract for fermentation by the microorganism, and

(iii) a neutralizing agent comprising a food-grade acid or an alkali metal hydroxide;

(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food;

(c) removing the aqueous medium from the uncooked processed food in the fermenter through the outlet strainer;

(d) washing the uncooked processed food from step (c); and

(e) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;

wherein no sugars are added to the processed food through steps (a) to (e).

21. The process of Claim 20 wherein the cooked food is selected from the group consisting of potato chips, tortilla chips, pretzels, crackers, baked goods, fried breads, processed cereals and French fries.

22. The process of Claim 20 wherein the uncooked processed food is potato slices.

23. The process of Claim 20 wherein the microorganism is a yeast.

24. The process of Claim 20 wherein the microorganism is a lactic acid producing microorganism.

25. The process of Claim 20 wherein at the end of the fermenting the aqueous medium has a pH between about 4 and 5.

26. The process of Claim 1 wherein the uncooked processed food added in step (a) comprises less than 0.1 wt.% glucose.

27. The process of Claim 1 wherein the uncooked processed food added in step (a) comprises less than 0.1 wt.% fructose.

28. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:

(a) adding a raw, uncooked processed food comprising asparagine, sugars, and less than 0.1 wt.% fructose to a fermenter containing an aqueous medium having a pH between about 4 and 8, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises:

(i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food,

(ii) yeast extract for fermentation by the microorganism, and

(iii) a neutralizing agent;

(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food; and

(c) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;

wherein no sugars are added to the processed food through steps (a) to (c).

29. A process for reducing acrylamide production from a reaction of free asparagine and sugars in a cooked, starch based processed food, the process comprising:

(a) adding a raw, uncooked processed food comprising asparagine, sugars, and less than 0.1 wt.% glucose to a fermenter containing an aqueous medium having a pH between about 4 and 8, wherein the aqueous medium contains the uncooked processed food and the aqueous medium comprises:

(i) a microorganism used for food fermentations for metabolizing sugars in the uncooked processed food,

(ii) yeast extract for fermentation by the microorganism, and

(iii) a neutralizing agent;

(b) agitating the aqueous medium while fermenting the uncooked processed food in the aqueous medium so as to ferment the sugars in the uncooked processed food sufficiently to reduce the acrylamide production upon cooking of the uncooked processed food; and

(c) baking or frying the uncooked processed food, thereby forming a fermented and cooked food that contains less acrylamide than without the fermentation;

wherein no sugars are added to the processed food through steps (a) to (c).

30. The process of Claim 29 wherein the uncooked processed food added in step (a) comprises less than 0.1 wt.% fructose.

31. The process of Claim 29 wherein the uncooked processed food added in step (a) comprises each of fructose, glucose, sucrose, maltose, and lactose at levels less than 0.1 wt.%.

32. The process of Claim 29 wherein the fermented and cooked food that contains less acrylamide than without the fermentation has an acrylamide reduction of about 50% or more.

33. The process of Claim 29 wherein the fermented and cooked food that contains less acrylamide than without the fermentation has an acrylamide reduction of about 50% to about 80%.

34. The process of Claim 29 wherein the fermented and cooked food that contains less acrylamide than without the fermentation has an acrylamide reduction of about 70% to about 80%.

IX. Evidence Appendix

Attached hereto is the Rule 1.132 Declaration of Aziz C. Awad dated September 11, 2008 ("Awad Declaration") as previously submitted along with Amendment "A" filed on September 12, 2008.

X. Related Proceedings Appendix

None.

PATENT

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Serial No.:	10/679,714
Applicant:	A. Awad
Filed:	October 6, 2003
Title:	REDUCTION OF ACRYLAMIDE FORMATION IN COOKED STARCHY FOODS
Group Art Unit:	1794
Confirmation No.:	2884
Customer No.:	21036
Examiner:	Viren A. Thakur
Attorney Docket No.:	Awad-George 4.1-7

DECLARATION OF AZIZ C. AWAD UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

I, Aziz C. Awad, the inventor in the above application, state as follows:

[0001] I hold a Ph.D. (2000) in Food Science (Food Chemistry major) from Michigan State University. My research areas include lipid and protein chemistry with a focus on the preservation and disinfection of food products using natural antimicrobial agents. I hold several patents and have many publications. I have several professional memberships in a variety of scientific fields: Institute of Food Technologists, American Heart Association, American Oil Chemist Society, and American Chemical society. I am the head of the research team at Mandala Technologies, LLC (Farmington Hills, MI), performing chemical and biochemical research related to food processing and antimicrobial products.

[0002] I am familiar with the contents of the above-identified application and the references cited in the rejection of the current claims. I make this declaration to

provide facts related to the application in general and the interpretation of the applied references.

[0003] Acrylamide Formation and Browning: The office action incorrectly concludes that the reduction of acrylamide is solely and directly tied to the reduction in browning. *See* p. 4-5 of the action. However, the absence of browning does not imply an absence of acrylamide formation. In fact, the observed acrylamide reductions according the claimed processes (Example 5, Tables 8 and 9) at a reducing sugar level of <0.1% (where no browning is observed) and at an optimal pH of 6-7 (i.e., a pH that enhances the for yeast/bacterial growth for fermentation) were 23% and 20%, respectively. However, when the pH was reduced to 4 the acrylamide reduction was increased to 74% without any change in the amount of reducing sugars (<0.1%). Surprisingly, at lower pH, the acrylamide reduction was much higher than that observed at the optimal pH (6-7) for microbial growth, even though at all pHs the amount of reducing sugar was the same <0.1%. These results indicate that the acrylamide content in potato chips is not solely related to their brown color. The higher acrylamide reduction obtained at pH 4 indicates that a low pH has an effect on the acrylamide reduction along with microbial fermentation, regardless of the amount of reducing sugars. Therefore, no browning does not mean no acrylamide formation in products produced according to Hilton's invention as the office action asserts.

[0004] Commercially available food products further illustrate that the formation of acrylamide is not exclusively related to browning. Frito-Lay (i.e., the assignee of Hilton), other potato chip manufacturers, and major fast food chains (e.g, McDonald's, Wendy's, and Burger King) settled a law suit with the State of California for not warning people about the presence of high levels of acrylamide in their products. R. Dillon, "Settlement will reduce carcinogens in potato chips," Associated Press, August 1, 2008, p. 1-2 ("Dillon") (attached). Frito-Lay's classic potato chips have a great bright color with no browning whatsoever, yet their acrylamide content ranges from about 250 ppb to about 550 ppb. "Survey Data on Acrylamide in Food: Individual Food Products," FDA Center for Food Safety and Applied Nutrition, July 2006, p. 4-5 ("Acrylamide Survey") (attached). Lay's Original Naturally Baked Crisps have an even higher amount of acrylamide: 1096 ppb (Acrylamide Survey, p. 5), yet their color is also bright with no browning whatsoever. Thus, the fact that a food product has been prepared in such a way to eliminate browning in no way implies that acrylamide also has been eliminated.

[0005] Yeast Extract: Yeast extract, which is the water soluble component of the yeast cell, is mainly protein, lacks the acrylamide precursor asparagine, and contributes only a small amount of carbohydrate (0.03 to 0.06%, average of about 0.04%).

[0006] The office action asserts that it would have been obvious to add a yeast extract to the system of Hilton to provide a nutrient source for Hilton's microorganisms. Hilton uses potatoes having an initially high reducing sugar content, so there would have been no reason to add a second nutrient source (i.e., the yeast extract) in addition to the pre-existing nutrient source (i.e., natural sugar content of the potatoes). Specifically, Hilton's fermentation need only take place as long as there are available sugars, and neither Hilton nor the other applied references recognizes the desirability of reducing components other than sugar (e.g., asparagine and acrylamide). In the examples of the present application, raw foods that were generally low in sugar were used. Thus, the yeast extract provided a nutrient source to allow the microorganisms to reduce other acrylamide precursors (e.g., asparagine or others). In contrast, Hilton's potatoes naturally contain a reducing sugar nutrient source, and there would have been no reason to add a redundant nutrient source. Further, the addition of yeast extract to Hilton could have been counterproductive. Specifically, the yeast extract represents a competing nutrient source in Hilton's system (i.e., in addition to the potato's natural sugar content), thereby limiting the rate of sugar reduction by Hilton's yeast due to the presence of the competing nutrient source. In particular, the yeast extract likely would be preferentially consumed before the reducing sugars (i.e., if added to Hilton's system), because the yeast extract would be more readily available in the fermentation medium than the reducing sugars. The yeast extract is dissolved or suspended in the aqueous medium; however, the reducing sugars must leach out of the potatoes to the aqueous medium before they are acted on by the microorganisms.

[0007] Moreover, whenever dry yeast extract is used in the applied references, it was used in combination with other growth-promoting ingredients. For example, the media in the *Catalog of Bacteria and Bacteriophages* contain sugar sources in addition to the yeast extract: skim milk (containing, e.g., lactose; medium #17) and glucose (medium #1006). Similarly, the medium from "Yeast Media, Solutions, and Stocks" adds glucose to its yeast extract. Champagnat also used yeast extract with

other nutrient ingredients as part of a medium containing paraffinic hydrocarbons of petroleum origin. Thus, identifying the use of dry yeast extract without an additional nutrient source (e.g., additional sugar as recited in the claims) as a fermentation aid in the claimed process is not taught or suggested by the applied references.

[0008] Fermentation Medium pH: The office action asserts that the use of an acid to adjust the pH of a medium is well known, for example relying on the *Catalog of Bacteria and Bacteriophages* and its disclosure of two aqueous media having pH values adjusted to 7 and 6.2 (See page 415 #17 and 452#1006). These are the conditions for the media that are optimal for the growth of the bacteria strain. However, what it is not known in the prior art until the development of the process described in the present disclosure is that using an acid to adjust the pH of a fermentation medium to a range that is below the optimal and even inhibitory pH range for the growth of the fermenting microorganisms can reduce the formation of acrylamide in the fermented food products regardless of the reduction of mono- and di-saccharides (acrylamide precursors). For example, the preliminary starting pH for initial experiments was selected to be pH 6, given that this value is near the optimal pH (pH 6-7) for the growth of microorganisms that ferment the mono- and di-saccharides (acrylamide precursors) in fresh potato slices. *See* Figure 1 and Examples 1-4 of the application specification. When the pH of the medium was adjusted to 4 or 5 (i.e., to a sub-optimal level in terms of the growth rate for the particular microorganisms tested), however, I unexpectedly found that the acrylamide reduction was significantly higher than the one observed at the optimal-growth pH. *See* Example 5 of the application (Table 8 (dry yeast) and Table 9 (bacterial cells)). Therefore, I identified and selected a pH of 4-5 as the optimal pH for the disclosed method, because the objective was to reduce acrylamide formation and not just to achieve optimal growth conditions for the fermenting microorganisms.

[0009] Further, the office action appears to equate the *reduction of acrylamide* with the *reduction of saccharides*. However, the two effects are completely different. The mechanism of acrylamide formation during cooking is not fully understood. While the Maillard reaction plays a role, it is not the only factor involved, as the results in Example 5 have shown. *See* Example 5 of the application (illustrating that variable acrylamide reduction is obtained in the absence of substantial acrylamide precursor (i.e., saccharide) reduction, given that the mono- and di-saccharide levels of the tested potatoes were all relatively low). Other mechanisms that are pH-dependent

might have a role, too. Thus, the strategy used in the office action (i.e., simply identifying processes and conditions in the applied references that lead to the reduction of saccharides (acrylamide precursors)), cannot lead the skilled artisan to the presently claimed processes that substantially reduce acrylamide formation.

[0010] Regarding the teachings in the applied references related to specific fermentation pH values, the office action appears to misinterpret multiple references. For example, Bechtle is cited for the disclosure of an initial fermentation pH of 4.9. Office action, p. 11. However, Bechtle's starting pH is the *native* pH of acid whey, which is well known to be between 5.1-5.6. Bechtle did not adjust the pH of the native acid whey prior to the fermentation, he used it as is. Moreover, Bechtle indicated that a pH of 4.4 to 4.9 is inhibitory to the growth of lactic acid bacteria. Bechtle, 14:16-25. Thus, Bechtle teaches the skilled artisan to operate at the optimal pH for microorganism fermentation and above a pH of 5. Similarly, Hagiwara's starting pH of 4-6 is also the native pH of its medium.

[0011] Surprisingly, however, at pH values between 4 and 5, the disclosed method exhibited the highest acrylamide reduction, even though such pH values are not optimal for fermentation (i.e., pH 6-7). This indicates that a low pH has an independent effect on the reduction of acrylamide regardless of the presence and/or disappearance of acrylamide precursors (mono- and di-saccharides), one of the reactants of the Maillard reaction. This further illustrates that acrylamide formation cannot be fully explained by the Maillard reaction and that some other mechanism probably operates to reduce acrylamide.

[0012] In the examples reported in the specification, 0.5% Dry Yeast Extract was used as a fermentation ingredient, before the onset of the fermentation to support the initial growth and activities of the fermenting microorganisms. At the 0.5% usage level of the examples, the small amount of carbohydrate in the yeast extract (0.04%, *see* ¶ [0005] above) consists of starch, fiber, and sugars; therefore, the amount of sugars coming from the yeast extract (0.5% in the fermentation medium) is substantially less than 0.04%. Moreover, the potato used to prepare the potato slices had a low level of reducing sugars (<0.1 wt.% glucose and <0.1wt.% fructose; page 10 Table 1), which is the snack industry standard. Therefore, due to the limited availability of substrate, the formation of lactic acid from the fermentation reaction did not cause a significant drop in pH from the original value that was fixed before the onset of the fermentation. In fact, there was no need to adjust the pH during

fermentation to its original value that was set before the onset of the fermentation. Consequently, the lower pH values recited in the claims cannot be obtained from lactic acid bacteria alone.

[0013] <u>Washing Limitation:</u> The process used by Hilton will not allow a washing step after the fermentation takes place unlike the recited process, because Hilton is using blanched mashed potatoes. The starting material used by Hilton in all the Examples (Example I to V) was blanched mashed potatoes, which was subsequently fermented with baker's yeast and dried to 48% solids content with a dough-like consistency. The post-fermentation blanched mashed potatoes cannot be washed to remove the fermenting yeast, because mashed potatoes are not washable and motivation to do so is simply not suggested by Hilton.

[0014] I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully Submitted,

A. Awad
Aziz C. Awad

09/11/08
Date